Food and Drug Administration
Center for Drug Evaluation and Research

ADVISORY COMMITTEE FOR PHARMACEUTICAL SCIENCE (ACPS)
May 3-4, 2005
CDER Advisory Committee Conference Room
5630 Fishers Lane
Rockville, MD

AGENDA

Day 1: Tuesday, May 3, 2005

8:30	**Call to Order**	Charles Cooney, Ph.D. Chair, ACPS
	Conflict of Interest Statement	Hilda Scharen, M.S. Executive Secretary, ACPS
8:45	**Introduction to Meeting** OPS Update	Helen Winkle Director, Office of Pharmaceutical Science (OPS), CDER, FDA
9:00	**Welcome and Opening Remarks**	Charles Cooney, Ph.D. Chair, ACPS
9:15	**Establishing Drug Release or Dissolution Specifications**	
	(1) Topic Introduction	Ajaz Hussain, Ph.D. Deputy Director, OPS, CDER, FDA
9:45	(2) Dissolution Measurement System: Current State and Opportunities for Improvement	Lucinda Buhse, Ph.D. Director, Division of Pharmaceutical Analysis, Office of Testing and Research (OTR), OPS, CDER, FDA
10:30	Break	
10:45	(3) Overview of Current Guidance Documents and Decision process: Biopharmaceutics Section I,	Mehul Mehta, Ph.D. Director, Division of Pharm. Evaluation Office of Clinical Pharmacology and Biopharmaceutics (OCPB), CDER, FDA
11:30	(4) Establishing Dissolution Specifications: Current Practice (CMC)	Vibhakar Shah, Ph.D. Chemist, Division of New Drug Chemistry II Office of New Drug Chemistry (ONDC), CDER, FDA
12:00	Lunch	
1:00	**Open Public Hearing**	

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Day 1: Tuesday, May 3, 2005 (continued)

1:30	**Establishing Drug Release or Dissolution Specifications (Continued)**	
	(5) Factors Impacting Drug Dissolution and Absorption: Current State of Science	Lawrence Yu, Ph.D. Director for Science, Office of Generic Drugs (OGD), OPS, CDER, FDA
2:00	(6) Summary of Tactical Plan	Ajaz Hussain, Ph.D.
3:00	Break	
3:15	**Committee Discussions and Recommendations**	
4:30	**Subcommittee Reports**	
	Clinical Pharmacology Subcommittee (via teleconference)	Jürgen Venitz, M.D., Ph.D. Chair, Clinical Pharmacology Subcommittee
5:00	**Adjourn**	

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Day 2: Wednesday, May 4, 2005

8:30	**Call to Order**	Charles Cooney, Ph.D. Chair, ACPS
	Conflict of Interest Statement	Hilda Scharen, M.S. Executive Secretary, ACPS
8:45	**Parametric Tolerance Interval Test for Dose Content Uniformity** Current update on the Working Group	Robert O'Neill, Ph.D. Director, Office of Biostatistics (OB), Office of Pharmacoepidemiology and Statistical Science (OPaSS), CDER, FDA
9:15	**Quality-by-Design and Pharmaceutical Equivalence**	
	(1) Topic Introduction	Ajaz Hussain, Ph.D.
	(2) Using Product Development Information to Extend Biopharmaceutics Classification System-based Biowaviers	Ajaz Hussain Ph.D.
10:30	Break	
10:45	(3) Using Product Development Information to Address the Challenge of Highly-variable Drugs	Lawrence Yu, Ph.D.
	(4) Using Product Development Information to Support Establishing Therapeutic Equivalence of Topical Products	Robert Lionberger, Ph.D. Chemist, OGD, OPS, CDER, FDA
12:00	Lunch	
1:00	**Open Public Hearing**	
2:00	**Quality-by-Design and Pharmaceutical Equivalence** (Continued)	
	(5) Summary of plan	Ajaz Hussain, Ph.D.
	Committee Discussion and Recommendations	
3:00	Break	

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Day 2: Wednesday, May 4, 2005 (continued)

3:15	**Criteria for Establishing a Working Group for Review and Assessment of OPS Research Programs**	
	(1) CBER Peer Review Process for Researchers/Reviewers	Kathleen A. Clouse, Ph.D. Acting Director, Division of Monoclonal Antibodies, Office of Biotechnology Products (OBP), OPS, CDER, FDA
	(2) CDER Peer Review Research	Jerry Collins, Ph.D. Director, Laboratory of Clinical Pharmacology, Office of Testing and Research (OTR), OPS, CDER, FDA
	Committee Discussion and Recommendations	
4:30	**Conclusion and Summary Remarks**	Ajaz Hussain, Ph.D. Helen Winkle
5:00	**Adjourn**	